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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/281,474	03/30/1999	MILIND RAJOPADHYE	DM-6958	7274

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EXAMINER

JONES, DAMERON LEVEST

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 07/02/2002

22

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application N .

09/281,474

Applicant(s)

RAJOPADHYE ET AL.

Examiner

D. L. Jones

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 10/16/00; 3/5/02; and 5/7/02.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) 36-47 and 51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-35 and 48-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10&20 . 6) ☐ Other:

Art Unit: 1616

### **ACKNOWLEDGMENTS**

1. The Examiner acknowledges receipt of Paper No. 18, filed 3/5/02, wherein Group 12 was elected with traverse. The traversal is on the basis that Groups 12, 29, 46, and 68 are not distinct inventions. Applicant's arguments have been found persuasive. Therefore, *modified Group 12* contains claims 1-35 and 48-50. Furthermore, it should be noted that the restriction requirement is still deemed proper and is therefore made FINAL. In addition, it is noted that Applicant elected Example 1, page 92, for prosecution.

### **APPLICANT'S INVENTION**

2. Applicant's invention is directed to compounds/compositions and uses thereof comprising a chelator, peptide, linking group (optional), alpha(v)beta(3) targeting moiety, and a metal (optional).

Note: It should be noted that *modified Group 12* has only been examined to the extent that it reads on the elected group. Furthermore, it should be noted that the full scope of *modified Group 12* has been examined.

### **WITHDRAWN CLAIMS**

3. Claims 36-47 and 51 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention/species.

## **DOUBLE PATENTING REJECTIONS**

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-35 and 48-50 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-36 and 56-139 of copending Application No. 09/465,300. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a targeting moiety, chelator, peptide, optionally a metal, and

Art Unit: 1616

optionally a linker. In particular, the claims differ in that 09/465,300 refer to their peptide as a 'non-peptide'. However, in the specification a 'non-peptide' is defined as a compound having preferably less than three amide bonds in the backbone core of the targeting moiety or preferably less than three amino acids/amino acid mimetics in the targeting moiety. Thus, the instant invention encompasses peptides having more than three amino acids..

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 1-35 and 48-50 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-40, 54, and 55 of copending Application No. 09/466,582. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a targeting moiety, chelator, peptide, optionally a metal, and optionally a linker. In particular, the claims differ in that 09/466,582 refer to their peptide as a 'non-peptide'. However, in the specification a 'non-peptide' is defined as a compound having preferably less than three amide bonds in the backbone core of the targeting moiety or preferably less than three amino acids/amino acid mimetics in the targeting moiety. Thus, the instant invention encompasses peptides having more than three amino acids..

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Art Unit: 1616

7. Claims 1-35 and 48-50 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7, 11-13, and 17-35 of copending Application No. 09/599,364. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a targeting moiety, chelator, peptide, optionally a metal, and optionally a linker. In particular, the claims differ in that 09/599,364 refer to their peptide as a 'non-peptide'. However, in the specification a 'non-peptide' is defined as a compound having preferably less than three amide bonds in the backbone core of the targeting moiety or preferably less than three amino acids/amino acid mimetics in the targeting moiety. Thus, the instant invention encompasses peptides having more than three amino acids..

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 1, 2, 11-15, 19-21, 23, 25, 27-29, 31-35, and 48-50 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 12-14, 20-23, 25, 27-29, 31-39, 46, and 48 of copending Application No. 09/281,209. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a targeting moiety, chelator, peptide, optionally a metal, and optionally a linker. In particular, the claims differ in that 09/281,209 refer to their peptide as a 'non-peptide'. However, in the specification a 'non-peptide' is defined as a compound having

Art Unit: 1616

preferably less than three amide bonds in the backbone core of the targeting moiety or preferably less than three amino acids/amino acid mimetics in the targeting moiety.

Thus, the instant invention encompasses peptides having more than three amino acids..

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 1-5, 7, 11-13, and 48 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 58-65 of copending Application No. 09/948,807. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a targeting moiety, chelator, peptide, optionally a metal, and optionally a linker. In particular, the claims differ in that 09/948,807 discloses specific species.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### **103 REJECTIONS**

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1616

11. Claims 1, 2, 11-15, 17, 19-23, 25, 27, 28, 31-35, 48, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palladino et al (US Patent No. 5,780,426).

**Palladino et al** disclose cyclic peptide inhibitors of diseases involving alpha(v)beta(3). Peptides pharmaceuticals and uses thereof are also disclosed. Therapeutic uses for the peptides include treating diseases such as cancer, osteoporosis, restenosis, and angiogenic-based disorders (see entire document, especially, abstract; columns 3-4, bridging paragraph). In addition, Palladino et al disclose (1) the peptides may be labeled with a radioisotope (e.g., 125I or 131I) [column 6, lines 37-55; column 20, line 18 - column 21, lines 12]. Enhancers such as chelators may also be present in the compositions (columns 16-17, bridging paragraph). (2) Diagnostic kits comprising the compositions may be generated as well (column 21, lines 23-55).

While, Palladino et al does not disclose a specific species having all of the components as set forth in Applicant's independent claims 1 and 11, it would have been obvious to one of ordinary skill at the time the invention was made to generate a compound and uses thereof comprising an alpha(v)beta(3) targeting moiety, chelator, and optionally a linker and metal because Palladino et al disclose each component, as claimed by Applicant, may be present with their compound/composition.

## **SPECIFICATION**

12. The disclosure is objected to because of the following informalities: the specification does not contain a heading titled 'Brief Description of the Drawings' and a description of the drawings.



Appropriate correction is required.


**COMMENTS/NOTES**

13. Applicant is respectfully requested to cancel all subject matter not directed to the non-elected invention.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (703) 308-4640. The examiner can normally be reached on Mon.-Fri. (alternate Mon.), 6:45 a.m. - 4:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose' Dees can be reached on (703) 308- 4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
D. L. Jones  
Primary Examiner  
Art Unit 1616

June 24, 2002